

**REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

**I. CLAIM STATUS AND AMENDMENTS**

Claims 1-16 were pending in this application when last examined.

Claims 5-16 were withdrawn.

Claims 1-4 have been examined on the merits and stand rejected.

Claims 2 and 4 have been amended to incorporate the subject matter of claims 1 and 3, respectively. No new matter has been added.

Claims 1, 3 and 5-10 have been cancelled without prejudice or disclaimer thereto.

Applicants reserve the right to file a continuation or divisional on any cancelled subject matter.

Claims 2, 4 and 11-16 are pending upon entry of this amendment.

Upon allowance of the elected invention, please consider the possibility of rejoinder of withdrawn claims 11-16 with the elected invention.

**II. ENABLEMENT REJECTION - DEPOSIT OF MICROORGANISMS**

On pages 3-6 of the Office Action, claims 2 and 4 were again rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement for deposited hybridoma K8223 (FERM BP-8334) on the basis that the Deposit Receipt submitted with the last response is not in English.

Attached herewith is an English translated Deposit Receipt for the Mouse-Mouse hybridoma K8223 (FERM BP-8334) as evidence that the hybridoma was deposited under the terms of the Budapest Treaty.

In view of the above and the statements made in the last response, the 112, first paragraph, enablement rejection of claims 2 and 4 is untenable and should be withdrawn.

### **III. WRITTEN DESCRIPTION REJECTION**

On pages 6-14 of the Action, claims 1 and 3 were again rejected under 35 U.S.C. § 112, first paragraph, on the basis that the Specification lacks written description support for the claimed genus of antibodies that recognize proliferative human hepatocytes.

It is again respectfully submitted that the Specification provides full written description support for the genus of claimed antibodies in view of the various methods for obtaining the claimed antibody disclosed throughout and the exemplified antibodies produced in the examples. Furthermore, the procedures for producing a monoclonal antibody are conventional and well known in the art. Given such disclosure, one of skill in the art could easily produce and test for antibodies with the requisite ability to specifically recognize proliferative hepatocytes that exist in a hepatocyte population isolated from an adult human liver and have clonal proliferative ability and differentiation ability to functional hepatocytes. Consequently, one of skill in the art could obtain antibodies of the present invention other than those produced by hybridoma cell, Mouse-Mouse hybridoma K8223 (FERM BP-8334) by following the guidance in the disclosure for obtaining and testing antibodies with the requisite properties.

Nonetheless, for the sole purpose of expediting prosecution and without acquiescing to the rejection, the rejected claims have been cancelled, thereby obviating this rejection. Thus, the 112, first paragraph, written description rejection of claims 1 and 3 is untenable and should be withdrawn.

### **IV. ANTICIPATION REJECTION**

On pages 14-16 of the Action, claims 1 and 3 were again rejected under 35 U.S.C. § 102(b) as anticipated by Hillman et al. (Journal of Hepatology, Vol. 24, pp. 385-390, 1996)

For the sole purpose of expediting prosecution and without acquiescing to the rejection, the rejected claims have been cancelled, thereby obviating this rejection.

In view of the above, the 102(b) rejection of claims 1 and 3 is untenable and should be withdrawn.

**CONCLUSION**

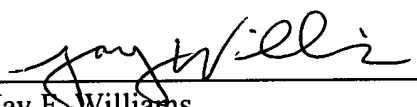
In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

Chise MUKAIDANI et al.

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Attorney Docket No. 2004\_1543A  
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**ATTACHMENTS**

1. English Translation of Deposit Receipt for Mouse-Mouse hybridoma K8223  
(FERM BP-8334).



INTERNATIONAL FORM

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSE OF PATENT PROCEDURE

RECEIPT IN THE NAME OF AN ORIGINAL DEPOSIT

issued pursuant to Rule 7.1 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified at the bottom of this page.

To Applicant:

Name Japan Science and Technology Corporation  
Address 4-1-8, Hon-cho, Kawaguchi-shi, Saitama

1. Identification of Microorganism	
(the identification reference given by the depositor) Mouse-Mouse hybridoma K8223	(Accession Number) FERM BP-8334
2. Scientific Description and Taxonomic Designation	
The following documents were attached to the microorganism of Item 1: <input checked="" type="checkbox"/> Scientific description <input checked="" type="checkbox"/> Taxonomic designation	
3. Accept and Deposit	
The International Depositary Authority accepted the microorganism of Item 1 that had been deposited on March 6, 2002 (date of original deposition).	
4. Acceptance of Transfer Request	
The International Depositary Authority accepted the microorganism of Item 1 on March 6, 2002 (date of original deposition), and accepted a request for transfer from the original deposit to the deposit under Budapest Treaty on March 20, 2003. (Transfer from FERM P-18752 deposited on March 6, 2002)	
5. International Depositary Authority	
Name: International Patent Organism Depositary National Institute of Advanced Industrial Science and Technology Dr. Syuichi Oka, Director Address: AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi Ibaraki-Ken 305-3566 Japan March 20, 2003	